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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,119	11/18/1999	PHILIPPE SAUER	P63712US0	4763

7590 01/28/2004
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WASHINGTON, DC 20004-2201

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/341,119

Applicant(s)

SAUER ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO reply is filed, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61-70 and 73-80 is/are allowed.
- 6) ☒ Claim(s) 71, 72 and 81-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The amendment filed November 6, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 61-83 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

Claims 71, 72 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastian et al (WO 95/21849 or U.S. Pat. 6,180,778 B1) in view of Segel (*Biochemical Calculations*, pp. 403-406 (Appendix IV), John Wiley & Sons, Inc., New York, 1976).

Bastian discloses solutions useful in purifying DNA, said solutions comprising chaotropic reagents (which may be thiocyanates), alcohols and buffers. See, e.g. discussion regarding lysis solutions at '778, col. 5, line 54 through col. 6, line 5; see also the various reagents disclosed by '778 at col. 7, line 59 through col. 8, line 18. Thus, the claims differ from the prior art in that the claims use a different chaotropic reagent than used in the prior art and a different buffer. However, the substitution of the known chaotropic agent, sodium thiocyanate, for the thiocyanate reagents in the Bastian references clearly must be considered the substitution

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of one known thiocyanate chaotropic agent for a known thiocyanate equivalent, and therefore obvious under § 103(a). Similarly, the substitution of a known buffer such as glycine (see, e.g. Segel at page 406) for the buffers used the Bastian references must clearly be considered a substitution of one known buffer for a known equivalent, and therefore obvious under § 103(a). Thus, absent a demonstration of something unexpected resulting from the use of these known equivalents, a holding of obviousness is required.

All of applicant's argument has been fully considered but is not persuasive of error. Applicant's response does not directly address this ground of rejection. However, as discussed above, Bastian discloses that solutions useful for purifying DNA contain alcohols, buffers and chaotropic agents, the very ingredients recited in applicant's product claims. Because the claims recite solutions containing buffers and chaotropic agents which would have been reasonably expected to have functioned equivalently to those in Bastian, the claims must be considered obvious under § 103(a), absent some demonstration of an unexpected result.

Claims 61-70 and 73-80 are allowed. Applicant's specification at page 10 defines the term "bacterial crude lysate" in unequivocal terminology:

The term bacterial crude lysate means lysed bacterial cells of which essentially no components are removed by a separation step in general respectively a precipitation step in particular.

The same paragraph points out that excluded separation steps include centrifugation and filtration. Specification, at page 11. ("Therefore, these methods require precipitation of genomic DNA and subsequent removal either by centrifugation or filtration to acquire a clean plasmid purification.") Because the meaning of the claim term "bacterial crude lysate" appearing in the specification clearly delineates between claimed subject matter and unclaimed subject matter, the rejection under § 112, second paragraph is withdrawn.

Similarly, because no prior art suggests a silica-based elution in the absence of purification steps excluded by applicant's definition of the term "bacterial crude lysate", the rejection under § 103(a) must be withdrawn. See Marko at page 383, disclosing a series of post lysis purification steps, including the centrifugation excluded by applicant's definition of the term "bacterial crude lysate." See also Little, at column 5, lines 60-62, disclosing as starting materials

"supernatants derived from the centrifugation step used to eliminate the cellular debris."

Lastly, in view of the fact that applicant has provided a process which allows for preferential binding to silica of circular nucleic acids over linear DNA, the enablement rejection is properly withdrawn. A claim may be properly enabled despite the fact that it encompasses non-operative embodiments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

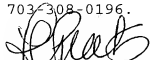
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP